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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,922	05/10/2001	Toshihiro Kuroita	10089/14	5846
26646	7590	11/21/2005	EXAMINER HUTSON, RICHARD G	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,922

Applicant(s)

KUROITA ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,25-28,30,32,33 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,25-28,30,32,33 and 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2005 has been entered.

Applicant's amendment of claims 1, 2, 4 and 6-12 and the cancellation of claims 35, in the paper of 10/21/2005, is acknowledged. Claims 1-12, 25-28, 30 and 32, 33 and 36-41 are still at issue and are present for examination. Applicants' arguments filed on 10/21/2005, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 25-28, 30 and 32, 33 and 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection was stated in the previous office action as it applied to previous claims 1-3, 25-28, 30 and 32, 33 and 35-41. In the previous rejection it was stated that the claims are indefinite in the recitation of "...**obtainable** from *Pyrococcus furiosus*, *Pyrococcus kodakaraensis* KOD1 or *Thermococcus litoralis*..." because it is unclear what applicants consider to be those DNA polymerases "obtainable from the recited species", and thus the claims are unclear. For the purposes of advancing prosecution the recitation has been interpreted as broadly as is reasonably possible, that is any DNA polymerase which is able to be isolated from the selected species including, those which must be recombinantly transformed into and then isolated from the recited species.

In response to this rejection applicants have amended the claims from "...**obtainable** from *Pyrococcus furiosus*, *Pyrococcus kodakaraensis* KOD1 or *Thermococcus litoralis*..." to "...**obtained** from *Pyrococcus* or *Thermococcus* genus...", however, applicants have not commented on the previously stated interpretation of the referred to recitation and because there is not much difference between "obtained" and "obtainable", this interpretation of the recitation remains, with the exception that rather than interpreting the recitation as any DNA polymerase which is able to be isolated from the selected species including, those which must be recombinantly transformed into and then isolated from the recited species, the recitation is interpreted as any DNA polymerase which is which has been obtained from the selected genres, including, those which have been recombinantly transformed into and then isolated from the recited genres.

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Claim 33 is further rejected under this statute because claim 33 is indefinite in that it is confusing and unclear in that claim 33 is directed to a modified thermostable DNA polymerase according to claim 1, wherein said DNA polymerase is thermostable DNA polymerase. The basis of the confusion is that it is unclear how claim 33 further limits claim 1 from which it depends. It appears that claim 33 is merely restating that the modified thermostable DNA polymerase must be thermostable, a limitation that it already had.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 25-28, 30, 32, 33 and 36-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to the claims previously. In response to this rejection applicants have amended claims 1, 2, 4 and 6-12, cancelled claim 35 and traverse the rejection as it applies to these newly amended claims.

It is again acknowledged that applicants previous traversal was found persuasive with respect to those modified thermostable DNA polymerases having the specified

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mutation if the DX₁EX₂X₃X₄H sequence, wherein said modified thermostable DNA polymerase is that unmodified thermostable DNA polymerase from *Pyrococcus furiosus*, *Pyrococcus kodakaraensis KOD1* or *Thermococcus litoralis* with the specifically recited mutation.

Claims 1-3, 25-28, 30 and 32, 33, 35-41 remain rejected under this statute on the basis that the claimed genus of modified thermostable DNA polymerases, wherein the genus is directed to those modified thermostable DNA polymerases having the recited modification in the DIETFYH or DIETFYH modification of those DNA polymerases "obtained from *Pyrococcus* or *Thermococcus* genus..." continues to be not adequately described.

As previously stated, applicants specification, however, only provides those representative species isolated from *Pyrococcus furiosus*, *Pyrococcus kodakaraensis KOD1* or *Thermococcus litoralis* encompassed by these claims. There continues to be inadequate disclosure of any particular structure to function/activity relationship in the disclosed species, sufficient to describe those claimed modified thermostable polymerases. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-3, 25-28, 30 and 32, 33 and 35-41 are further rejected under this statute on the basis that the modification of those DNA polymerases "obtained from ***Pyrococcus* or *Thermococcus* genus...**" are not supported by the specification at the time of filing and thus considered new matter (See also above 112 second paragraph rejection). Specifically, the genus of polymerases directed to any modified polymerase from ***Pyrococcus* or *Thermococcus* genus** is not supported by the specification at the time of filing.

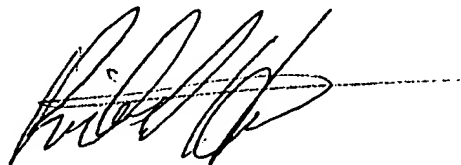
Claim 4-12 are rejected under this statute because a "modified thermostable DNA polymerase wherein said polymerase comprises the amino acid sequence of SEQ ID NO: 2, except that the amino acid sequence located at the 141- to 146-positions of SEQ ID NO: 2 is selected from DIETLY or DIETFY..." (See claim 4) is not supported by the specification at the time of filing and is thus considered new matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
11/08/2005